

Evaluation of 278 New Bluephase Style Light Curing Units Purchased Over Six Years

Keywords

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ABSTRACT

Objective: This study measured 278 new curing lights (LCUs) to determine if they met the manufacturer's specifications. *Materials and Methods:* Over a 6-year period, the light output from 278 Bluephase Style LCUs was measured before the LCUs were given to students (41 in 2017, 44 in 2018, 46 in 2019, 48 in 2020, 50 in 2021, and 49 in 2022). The radiant exitance (mW/cm^2) from each year was compared using ANOVA and Tukey-Kramer multiple comparisons test with adjustment for the unequal sample sizes ($\alpha=0.05$). The results were also compared against the manufacturer's stated radiant exitance of $1200 \text{ mW}/\text{cm}^2$. *Results:* The 278 LCUs delivered an average (\pm standard deviation) radiant exitance of $1203 \pm 16.7 \text{ mW}/\text{cm}^2$. The lowest radiant exitance was $1149 \text{ mW}/\text{cm}^2$ and the highest was $1257 \text{ mW}/\text{cm}^2$. Although there were statistically significant differences in the LCUs from each year, these values were within the manufacturer's tolerance of values of $\pm 10\%$. Approximately 13% of the emitted light was below 420 nm, and 87% was above 420 nm. *Conclusion:* These new LCUs were all multiple peak LCUs that emitted an average radiant exitance of $1,203 \text{ mW}/\text{cm}^2$ (range 1149 to $1257 \text{ mW}/\text{cm}^2$). Purchasers of the Style LCU can be confident that their new LCU will meet the manufacturer's specifications.

INTRODUCTION

Dentists depend on results from well-conducted studies when deciding what equipment to purchase and how to treat their patients, yet often, only one lot number or example of each product is used in a study. For instance, light curing units (LCUs) have become essential equipment in dental offices,¹ yet the question of how representative the LCUs used in these studies are compared to other LCUs of the same brand is not addressed.²⁻¹⁸ In addition, most studies do not measure the emission spectrum or the radiant exitance from the LCU with laboratory-grade equipment.¹⁹

In most countries, LCUs are classified as medical devices and should comply with standards set by the regulatory authorities.^{18,20,21} The International Organization for Standardization (ISO) standard 10650 for powered polymerization activators only requires LCUs to deliver a radiant exitance (tip irradiance) within $\pm 20\%$ of the manufacturer's claimed radiant exitance value.²² Thus, if the manufacturer states that the radiant exitance is $1200 \text{ mW}/\text{cm}^2$, the LCU would still meet the standard if it delivered 960 or $1440 \text{ mW}/\text{cm}^2$. However, this wide range in values ($\pm 20\%$) would most likely affect the outcome of research studies, or the clinical performance of the LCU.

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The International System of Units (SI) terminology and the ISO standard 10650 for powered polymerization activators describes the light output at the tip of a curing light as the radiant exitance.²² This is the same as the irradiance measured at the tip of the curing light. Although dentists are more familiar with the term irradiance rather than radiant exitance, the term radiant exitance shall be used in this article rather than irradiance except when referring to specific articles. For example, dentists rank a high irradiance (radiant exitance) as the second most important feature after portability when choosing which LCU to purchase,²³ and most dental manufacturers^{24,25} recommend delivering a minimum irradiance of 500 to 550 mW/cm² to photocure their resins.

After the COVID pandemic, it has been estimated that 68% of the dental supply market shifted to online sources.²⁶ One publication in 2022 also reported that 62.4% of the participants used social media to sell and/or buy dental equipment.²⁷ Consequently, many dental students and dental offices purchase lower-priced curing lights^{16–18,28} from online sellers who take no responsibility for the safety, reliability, reproducibility, or efficacy of the products they sell online.¹⁸ This is concerning because these budget devices may not have received approval and may lack the necessary safety testing and appropriate electrical safety certifications.¹⁸ These budget LCUs also often lack clear instructions for use, lack information who to contact in case of an untoward event with the device, they also often deliver an uneven light output (beam profile homogeneity) compared to more expensive lights from major manufacturers.^{15,16} The light output is often unstable, and their radiant exitance levels may decline without warning because the electronics in these LCUs may not compensate for the decrease in output from the battery during use, or as the temperature of the LED increases.^{17,29–31} The battery in some low-cost LCUs may even pose a potential fire hazard.³² Higher priced LCUs, such as those from Ivoclar, claim that their LCUs deliver an output that is $\pm 10\%$ of the stated radiant exitance³³ which is better than the ISO standard of $\pm 20\%$,²² but do these more expensive LCUs meet their claim?

The Bluephase Style from Ivoclar is a popular LCU, and it has been widely used in research studies.^{8–14} Since the authors could find no information regarding the consistency in the light output from the same brand of LCU, this study evaluated 278 new Bluephase Style LCUs that had been purchased over a 6-year period. The hypothesis was that the radiant exitance (tip irradiance) would be within the $\pm 10\%$ tolerance stated by the manufacturer.

METHODS AND MATERIALS

After going through an open tendering procedure, (<https://dal.bidsandtenders.ca/Module/Tenders/en>), Dalhousie University made the decision to purchase Bluephase Style LCUs from Ivoclar Vivadent from 2017 to 2022 for the first-year dental students to use and keep when they left. The authors did not decide which lights the University would purchase.

From 2017 to 2022, a total of 278 brand-new LCUs were purchased, and examined before they were given to the students (41 lights in 2017, 44 in 2018, 46 in 2019, 48 in 2020, 50 in 2021, and 49 in 2022). The non-consecutive serial numbers of the LCUs ranged from 1100012176 to 1100042942.

The radiant power (mW) and emission spectrum (mW/nm) were measured using previously described methods.¹⁵ In summary, a 6-inch integrating sphere (Labsphere, North Sutton, NH, USA) was connected to a pre-calibrated fibre-optic spectrometer (Flame-T, Ocean Insight, Orlando, FL, USA) to measure the power (mW) and the radiant spectral power (mW/nm) from these brand new LCUs before they were given to the students. The same operator and equipment were used to measure each LCU with the tip of the LCU centered over a 12.5 mm diameter entrance into the integrating sphere (*Figure 1*). Thus, all the light from the LCU entered into the sphere.



Figure 1: Bluephase Style lights measured using a 6" integrating sphere attached to a fiberoptic spectrometer

The active emission area (cm²) of each LCU tip was calculated by measuring the internal diameter of five light tips with a digital calliper (Mitutoyo, Canada Inc, Mississauga, ON, Canada). The mean (\pm standard deviation) internal tip diameter was 8.9 ± 0.01 mm, and the same tip area of 62.2 mm² was used to calculate the radiant exitance (mW/cm²) from all the LCUs.

STATISTICAL ANALYSIS

The mean and range of the power and radiant exitance (mW/cm²), standard deviation, and coefficient of variation from the 278 new Bluephase Style LCUs over the six years were calculated. After checking the data for normality using the Shapiro-Wilk test, the radiant exitance (mW/cm²) results from each year were compared using ANOVA, followed by Tukey-Kramer multiple comparisons test with a correction for the unequal numbers of LCUs tested each year ($\alpha=0.05$) The results were

also compared against the manufacturer’s stated radiant exitance claim³³ of 1200 mW/cm² +/-10% (1080-1320 mW/cm²). The emission spectra were compared visually, and the mean ratios of the amount of light emitted below and above 420 nm were reported for each year.

RESULTS

The number of LCUs tested each year, mean radiant power, mean radiant exitance, standard deviation and coefficient of variation are reported in Tables 1 and 2. The Shapiro-Wilk test

for normality had a p-value of 0.801, indicating that the results were normally distributed. The mean radiant exitance from the 278 new Style lights was 1203 mW/cm², the lowest radiant exitance was 1149 mW/cm², and the highest was 1257 mW/cm². The highest coefficient of variation was 1.5%. These values were well within the manufacturer’s tolerance of 1200 mW/cm² ± 10% (1080 to 1320 mW/cm²). However, ANOVA and the Tukey-Kramer showed that there were significant differences in the radiant exitance values recorded in some, but not all years (p<0.001). Table 3 shows how the results in 2017, 2018, 2019 and 2020 were more consistent than in 2021 and 2022, although the mean values were all very similar each year (Tables 1 and 2).

Table 1. Mean, minimum, maximum, and range in the radiant power (mW) of the new LCUs tested each year.

	Year Tested						Total
	2017	2018	2019	2020	2021	2022	
Number of LCUs	41	44	46	48	50	49	278
Power (mW)							
Minimum	736	732	736	728	715	726	715
Maximum	770	782	770	787	757	767	787
Range	33.8	50.1	33.9	58.6	42.3	41.5	71.8
Mean	753	752	752	760	745	738	750
Std. Deviation	7.8	11.3	6.8	11.4	7.1	8.3	11.4
Lower 95% CI of mean	750	748	750	757	743	736	748
Upper 95% CI of mean	755	755	754	764	747	741	751
Coefficient of variation	1.04%	1.51%	0.909%	1.50%	0.95%	1.13%	1.51%

Table 2. Mean, minimum, maximum, and range in the radiant exitance (mW/cm²) of the new LCUs tested each year.

	Year Tested						Total
	2017	2018	2019	2020	2021	2022	
Number of LCUs	41	44	46	48	50	49	278
Radiant exitance (mW/cm²)							
Minimum	1183	1176	1183	1158	1149	1166	1149
Maximum	1238	1257	1237	1251	1217	1233	1257
Range	54.3	80.6	54.5	93.2	68.0	66.6	107.6
Mean	1210	1208	1209	1209	1197	1187	1203
Std. Deviation	12.57	18.22	10.99	18.15	11.41	13.38	16.68
Lower 95% CI of mean	1206	1203	1205	1204	1194	1183	1201
Upper 95% CI of mean	1214	1214	1212	1214	1200	1191	1205
Coefficient of variation %	1.03	1.50	0.90	1.50	0.95	1.13	1.39

Table 3. Tukey-Kramer multiple comparisons test comparing the lights tested each year (2017-2022).

Tukey-Kramer multiple comparisons test	Mean Diff.	95.0% CI of diff.	Summary	Adjusted P Value
2017 vs. 2018	1.72	-7.26 to 10.69	ns	0.9940
2017 vs. 2019	1.24	-7.64 to 10.13	ns	0.9986
2017 vs. 2020	0.99	-7.81 to 9.78	ns	0.9995
2017 vs. 2021	12.78	4.06 to 21.49	***	0.0005
2017 vs. 2022	22.94	14.18 to 31.69	****	<0.0001
2018 vs. 2019	-0.47	-9.20 to 8.25	ns	>0.9999
2018 vs. 2020	-0.70	-9.36 to 7.90	ns	0.9999
2018 vs. 2021	11.06	2.51 to 19.61	**	0.0034
2018 vs. 2022	21.22	12.63 to 29.81	****	<0.0001
2019 vs. 2020	-0.25	-8.79 to 8.28	ns	>0.9999
2019 vs. 2021	11.53	3.08 to 19.98	**	0.0016
2019 vs. 2022	21.69	13.20 to 30.19	****	<0.0001
2020 vs. 2021	11.79	3.43 to 20.15	***	0.0009
2020 vs. 2022	21.95	13.55 to 30.35	****	<0.0001
2021 vs. 2022	10.16	1.85 to 18.47	**	0.0069

Figure 2 illustrates the emission spectra from 278 examples of the Bluephase Style lights. The results confirmed that the Style is a multiple peak polywave® LCU. Some differences in the emission spectra were noted each year, but 2022 appeared to be more uniform. Table 4 reports the mean power emitted below and above 420 nm for each year. The ratios of the power emitted below 420 nm (violet) and above 420 nm (blue) ranged from 12.6% violet:87.4% blue in 2020 to 14.0% violet:86% blue in 2022.

DISCUSSION

This study was designed to analyze and compare the radiant power, emission spectrum, and radiant exitance for 278 new Bluephase Style LCUs over six years (Tables 1 and 2). The study aimed to assess the level of confidence dentists can have in the quality of LCUs when purchasing this LCU from this manufacturer. After comparing the results from 278 LCUs, the results of this study should reassure dentists that the stated output of 1200 mW/cm² from 278 Bluephase Style LCUs sold over a 6-year period is an accurate and consistent value from different examples of new Bluephase Style LCUs.

The 2018 ISO 10650 standard²² for measuring output from dental curing lights uses an optical spectrophotometer attached to an integrating sphere, as was used in the present study. The total emitted power is then divided by the area of the light tip

to produce an average radiant exitance (tip irradiance) across the tip of the curing light. According to this ISO standard,²² the radiant exitance in the 385 nm to 515 nm wavelength region should not exceed ,000 mW/cm². Below 380 nm, the radiant exitance should not be more than 200 mW/cm², and above 515 nm, it should not be more than 100 mW/cm². The Bluephase Style lights met this standard (Table 4).

Since manufacturers only report the output from their LCU as irradiance (radiant exitance) and not power, both the power and radiant exitance values from the Style LCUs are reported, and the comparisons were made between the claimed irradiance and the measured radiant exitance (tip irradiance) values. Ivoclar claims³³ that the Bluephase Style should emit a radiant exitance (irradiance) of 1200 mW/cm² ± 10%. This indicates that the acceptable range is between 1080 and 1320 mW/cm². Table 2 shows that the LCUs measured in this study had an overall average (± standard deviation) radiant exitance of 1203 ± 16.7 mW/cm², which was almost exactly the manufacturer's stated value of 1200 mW/cm². The lowest radiant exitance was 1149 mW/cm² and the highest was 1257 mW/cm². These values were within – 4.3% and + 4.8 % of the output stated by the manufacturer (1200 mW/cm²), all well within the manufacturer's tolerance of 1080 to 1320 mW/cm², and well within the ISO standard 10650²² of ± 20%. Table 2 also shows that the highest coefficient of variation was 1.5%, which was excellent, and the upper and lower 95% confidence

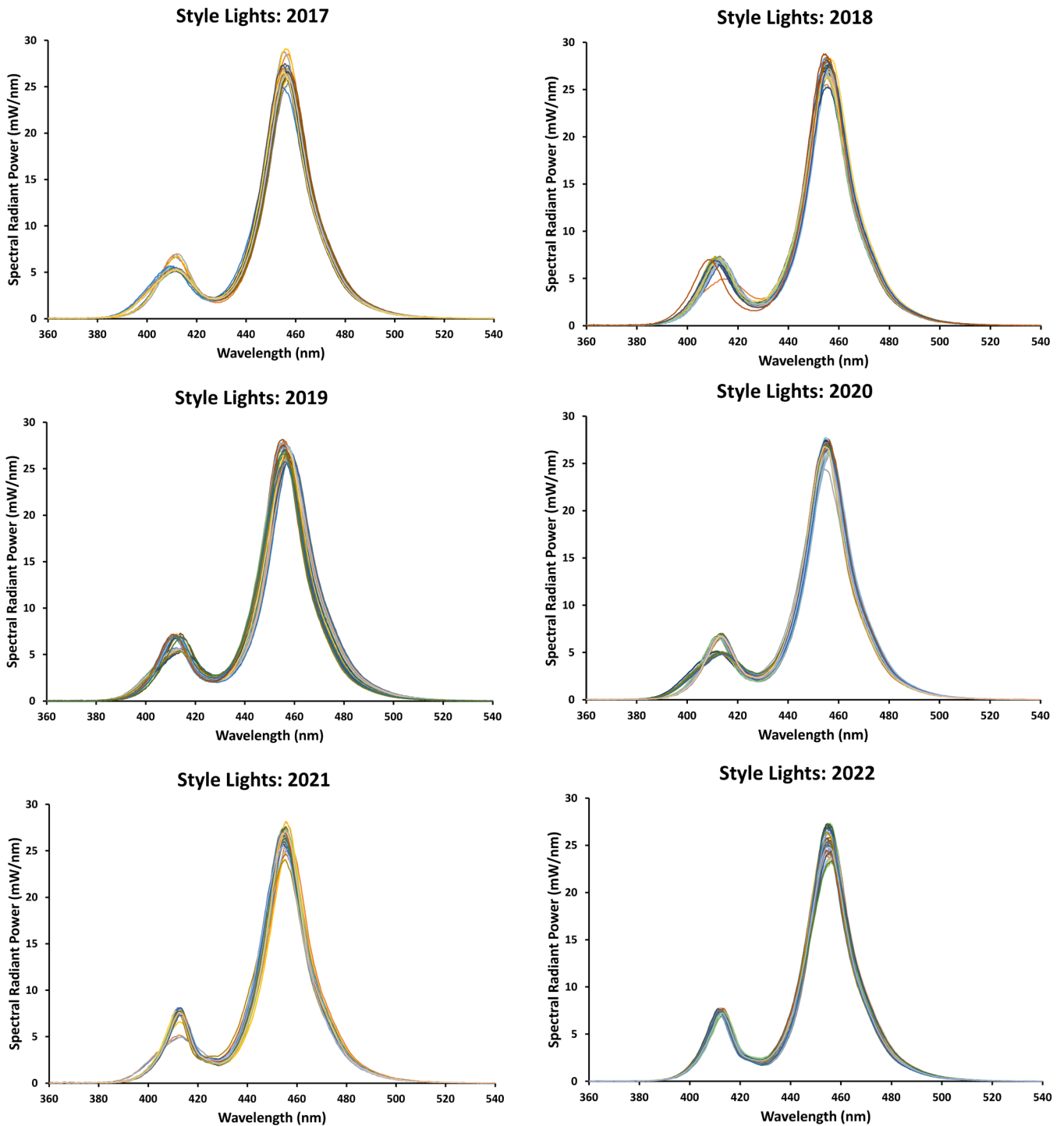


Figure 2: Emission spectra from the 278 examples of the Bluephase Style LCU.

intervals about the mean values were at most 10 mW/cm². The lowest radiant exitance was 1149 mW/cm² and the highest was 1257 mW/cm².

As shown in Figure 2, the Style is a multiple peak polywave[®] LCU, and the range in the <420 nm (violet) :>420 nm (blue) emitted powers ranged between 12.6% violet:87.4% blue in 2020, to 14.0% violet:86.0% blue in 2022 (Table 4). These small differences in the emission spectra from these lights over the 6-year period are most likely due to different production runs and batch numbers of the LED emitters used in the LCUs. Before they are sold, the LEDs undergo a binning process that

categorizes and groups the LED emitters based on their performance characteristics such as expected lifespan and emission spectra. Each bin represents a specific range or tolerance within these parameters, and the tighter the tolerances, the better the quality control, but the more the LEDs cost.³⁴ This sorting process is crucial for manufacturers to ensure that the LEDs they use are suitable for their intended applications. Thus, the small differences in the emission spectra noted in the lights from the 6 years are simply a reflection of the LED binning process, and this result is to be expected from LEDs and dental LCUs purchased over a 6-year period.

Table 4. Mean power (mW), (%) contribution and radiant exitance (mW/cm²) emitted below 420 nm and above 420 nm from the LCUs measured each year.

Range	Year Tested											
	2017		2018		2019		2020		2021		2022	
	mW	(mW/cm ²)	mW	(mW/cm ²)	mW	(mW/cm ²)	mW	(mW/cm ²)	mW	(mW/cm ²)	mW	(mW/cm ²)
	(% of total power)		(% of total power)	(% of total power)	(% of total power)	(% of total power)	(% of total power)	(% of total power)	(% of total power)	(% of total power)	(% of total power)	(% of total power)
Violet 350-420 nm	101.5 (13.5)	163	103.0 (13.7)	166	99.7 (13.3)	160	95.9 (12.6)	154	100.3 (13.5)	161	103.1 (14.0)	166
Blue >420 nm	651.5 (86.5)	1047	649.0 (86.3)	1043	652.3 (86.7)	1049	664.1 (87.4)	1068	644.7 (86.5)	1036	634.9 (86.0)	1021
Total	753.0	1211	752.0	1209	752.0	1209	760.0	1222	745.0	1198	738.0	1186

There are also several other potential reasons to account for these observed differences. The tip diameters of all 278 LCUs were not measured individually. Instead, the same tip diameter of 8.9 mm was used to calculate the irradiance from all the LCUs, but a future study could measure each light tip, calculate the area of each tip, and then use that value to calculate the irradiance. However, since the standard deviation in the tip diameter of 5 representative light tips was 0.01 mm, this limitation was considered small enough to be acceptable. A larger source of potential error was the calibration accuracy of the spectrometer. The manufacturers of the test equipment (Labsphere and Ocean Insight) state that the calibration accuracy is at best $\pm 3\%$ in the 350 to 500 nm wavelength range.³⁵ How Ivoclar calibrated the LCUs is unknown, and some error may have been introduced when calibrating the LCU by the manufacturer. The same operator made all 278 measurements for this study and the equipment used to measure the LCUs measurement equipment was recalibrated each year, or in the equipment used to measure the LCUs. Thus, the small differences in radiant power, but not the emission spectra, could be due to operator error to due to calibration inaccuracies during the manufacturing process.

This study only looked at new LCUs from one manufacturer. Since the ISO 10650 standard²² states that the output from same brand of LCU can be $\pm 20\%$, other brands or LCUs that have been used for several hours may not produce the same results. It is recommended that the total power, spectral radiant power, and irradiance should be measured and reported in research studies. However, it is important to acknowledge that although there were some statistically significant differences among the radiant exitant values, the -4.3% and $+4.8\%$ range (1149 to 1257 mW/cm²) of the radiant exitant values from these 278 new LCUs was well within the acceptable range specified by the manufacturer. Thus, dentists can be reassured that the output stated by Ivoclar for at least one brand of their new LCUs is accurate. Although not part of the

original study, the Bluephase Style LCUs provided to students in 2021 were retested in October 2023 using a Bluephase Meter II (Ivoclar) and a CheckUp device (BlueLight Analytics, Halifax, Canada) as part of an in-class exercise. The students had used these LCUs in both pre-clinical and clinical settings since they received the LCUs in September 2021. The mean radiant exitance calculated from the Bluephase II power results and divided by a tip area of 62.2 mm², was 1152 mW/cm², with a range of 1072 to 1198 mW/cm². The CheckUp device reported a mean radiant exitance of 1224 mW/cm², with a range of 1010 to 1274 mW/cm². Although an ANOVA, followed by the Tukey-Kramer multiple comparisons test revealed significant differences among the three measurements ($p > 0.05$), the radiant exitance values were very close to the mean value of 1197 mW/cm² (range of 1149 to 1217 mW/cm²) measured from these same LCUs when they were new in 2021 (Table 2). The consistency in the results across these three measurement techniques and the two-year time interval is highly encouraging for this brand of LCU. Any observed statistical differences are most likely due to the use of different measuring devices, or the fact that the students had used the LCUs for more than 2 years. However, further study is required to determine the effects of use on the light output from the Bluephase Style and other brands of LCUs.

CONCLUSIONS

1. Overall, the 278 new Bluephase Style LCUs had an average (\pm standard deviation) radiant exitance of 1203 \pm 16.7 mW/cm².
2. Although some statistical differences existed between the Bluephase Style LCUs purchased each year, the lowest radiant exitance was 1149 mW/cm² and the highest was 1257 mW/cm². These values were within -4.3% and $+4.8\%$ of the output stated by the manufacturer (1,200 mW/cm²).

3. Approximately 13% of the emitted light was below 420 nm, and 87% was above 420 nm from the Bluephase Style.
4. Users of this can be confident that there is a strong likelihood that a new Bluephase Style LCU will meet the manufacturer’s specifications.

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